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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,471	10/19/2001	Mark T. Martin	100391-02030	1031

35745 7590 04/10/2007

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NEW YORK, NY 10036

EXAMINER	
MEAH, MOHAMMAD Y	
ART UNIT	**PAPER NUMBER**
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER
	20070307

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

In response to applicants argument the previous final rejection is withdrawn and Examiner agrres to consider last final action after RCE as non-final action and resubmitted as NON-FINAL ACTION.

Office Action Summary	Application No.	Applicant(s)	
	10/039,471	MARTIN, MARK T.	
	Examiner	Art Unit	
	Mohammad Meah	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-20,23,26-29 and 32-45* is/are pending in the application.

4a) Of the above claim(s) *7-9 and 33-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 6, 10-20, 23-26, 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/28/06 has been entered.

Claims 7-9 and 33-45 and claims drawn to the invention of Group I not limited to the indicated specie are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/13/04 and 3/2/05.

The amendment filed 11/10/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicants argue that they have corrected Table 2 "using numbers provided in the NIH grant application", which was provided with the 11/10/05 amendment. They further state that MPEP 2163.07 states that "[a]n amendment to correct an obvious error does not constitute new matter", that the paragraph immediately preceding Table 2 refers to "concentrations" in the plural, that the data in the two columns differ from one another even though the columns are labeled identically and that one skilled in the art would appreciate the proper ranges from "Table 3 (providing 12 µg/mL and 111 µg/ml in lines 3

and 5 and from the specification, page 37, line 16 providing concentrations of 10 µg/ml and 0.12 µg/ml, and because the typo does not relate to the claimed subject matter and the correction does not affect the scope or enablement of the currently pending claims". To start with, applicants apparently intend to refer to line 16 of page 38, not page 37. Secondly, with the evidence provided to the surrounding parts of the specification and the NIH grant proposal, the examiner will allow the columns to be relabeled as 10 µg/mL and 100 µg/mL. However, as pointed out in the action of 1/30/06 and the advisory of 6/1/06, the amendment proposed 11/10/05 to Table 2 has the columns labeled "10 µM" and "100 µM", which are distinctly different from 10 µg/mL and 100 µg/mL.

Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6, 10-20, 23, 26-29 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicant argues essentially that working examples are not required and that the ordinary artisan could practice the instant invention reading the instant specification. Secondly it is argued that the references cited in the previous action to show the unpredictability of making catalytic antibodies explains the possible cause and effect of the results found and cites two references (Nevinsky, et al. and Stevenson, et al.) to show the high state of the catalytic antibody art. It is agreed that working examples are not required in patent applications, but for the reasons discussed in the last action, they are preferred due to the unpredictable nature of making catalytic antibodies. Secondly, it is pointed out that all of the examples in the two references referred to by applicant disclose the hapten used to make the catalytic antibody, which is not done by applicant's specification. It is further pointed out that these references are not of record in the instant application.

Claims 17-20, 23 and 26 have been amended to be drawn to a "non-naturally occurring enzyme". The specification does not teach nor enable one of ordinary skill in the art to make the "non-naturally occurring enzyme" of the instant claims. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicant argues that the specification teaches "[c]atalysts of biological origin such as enzymes" on page 7, line 25 and that the specification teaches that "[c]atalytic antibodies are especially preferred catalysts" on page 8, line 3. It is pointed out that "non-naturally occurring enzyme[s]" do not fall within the scope of enzymes of biological origin. Furthermore, a search of the original specification, claims and abstract did not find the

words "non-naturally occurring enzyme" and only one occurrence of the word "naturally", on page 7, line 8. It is maintained that not only does the specification not teach methods of modifying enzymes to non-naturally occurring ones, it does not provide even the mention of the words. It is maintained that undue experimentation would have been required to make such an enzyme.

Claims 1-3, 6, 10-20, 23, 26-29 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicant essentially repeats the arguments made in the amendment filed 11/10/05. In *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir., 1991), it is stated that "the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented " (emphasis added) (page 1116), citing *In re Gasteli*, 10 USPQ2d 1614. It is also stated that "[t]he invention is defined by the claims on appeal (page 1118), citing *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 128 USPQ 354.

It is maintained that applicant has not shown in the instant specification that they had possession of the claimed subject matter at the time the application was filed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
September 26, 2006